Message

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Subject: News Update:

Risk Policy Report - 06/23/2015

Despite Challenges, IRIS Staff Defend Plan To Assess PCB Mixtures' Risks

Posted: June 22, 2015

EPA staff is acknowledging the challenges in assessing the human health risks of exposure to mixtures of polychlorinated biphenyls (PCBs), in part due to the varied nature of the mixtures that occur in the environment and new data about their non-cancer risks, but an existing assessment may provide a template for the new effort.

There are 209 PCB congeners, chemicals that were developed and used starting about 1930 until EPA banned their use in 1979. EPA's planning and scoping document for its pending Integrated Risk Information System (IRIS) assessment of the human health risks of PCBs estimates that "more than 600 million [kilograms] of PCBs were commercially produced in the United States," due to their multitude of uses in electrical applications for insulating and inflammability, as well as other uses in paints, inks, coatings, sealants, caulks and others.

But the breadth of the number of congeners, and the fact that they persist in the environment in various mixtures, complicates EPA's efforts to craft an IRIS assessment. Industry stakeholders pressed IRIS staff on these challenges during a public meeting June 17-18 in Arlington, VA, to discuss the agency's draft scoping and planning document for the PCB assessment. *Relevant documents are available on InsideEPA.com. (Doc. ID: 182440)*

"I don't envy you people at EPA, there are so many choices and not much data in the tasks at hand," one speaker said during the meeting. "On the other hand, it's so important. Inhaled and higher-chlorinated, less dioxin-like PCBs are not in IRIS . . ."

An industry representative questioned whether EPA's efforts to assess non-cancer risks of exposure to PCBs, with a focus on ingestion and inhalation pathways is necessary, and given competing priorities and limited resources, whether IRIS' existing publications on PCBs are sufficient for the time being. EPA in 1996 published assessments containing reference doses (RfDs) for three Aroclors, the original, commercial form of PCBs.

"Since you already have RfDs for two Aroclors -- they might be sufficient and protective," suggested Nancy Beck, senior director of regulatory science policy at the American Chemistry Council. "Maybe you don't need a full assessment . . ."

"We thought about that," replied Geniece Lehmann, EPA's chemical manager for the PCB IRIS assessment. But "there is much more recent data" than what was available in the early 1990s, she continued. "So even if we were sticking with Aroclors, we'd want to update them." The newer data, she added, "would definitely change the" risk estimates for the Aroclors, but she added that she could not speculate on the magnitude of the changes.

Lehmann identified groups susceptible to PCBs exposure as recreational and subsistence fishers, Native Americans, occupants of PCB-contaminated buildings and breast-fed infants. PCBs were banned due to concerns over their health effects -- some are carcinogenic, and newer evidence suggests some pose non-cancer health risks as well -- and their persistence. PCBs are also bioaccumulative, magnifying up the food chain and accumulating in fish and other meats and fats.

IRIS program director Vincent Cogliano explained in response to other questioning from Beck that several EPA regional offices sought the non-cancer numbers from IRIS to relate to air concentrations measured in schools and other buildings, as well as to provide new benchmarks for fish consumption advisories.

"As you know, there are concentrations of PCBs in air in schools . . . As far as I know, no federal agency has a [benchmark] concentration of air levels [that is safe]," Cogliano replied. "We're trying to help answer a question a lot of people have with this."

Environmental exposures are generally to mixtures of PCBs, which are often different to the toxicity of individual Aroclors. The complexity of the mixtures, and the number of possibilities of mixtures, given the 209 congeners, led speakers throughout the meeting to question how EPA could advance a general PCBs assessment.
But EPA has already performed one IRIS assessment of multiple PCBs which may provide an approach for the new assessment to follow, an agency source says, pointing to a 1994 cancer assessment of several PCBs.

The 1994 assessment -- written by Cogliano -- includes toxicity studies of four PCBs: Aroclors 1260, 1254, 1242 and 1016. The assessment includes three different "tiers of human slope factors [cancer potency estimates for ingestion] for environmental PCBs," titled high risk, low risk and lowest risk. The assessment provides information for the circumstances in which the different slope factors should be used. Such an approach could perhaps be used in the new assessment of non-cancer risks, the source says.

IRIS assessors could calculate "different estimates from different segments of PCB mixtures and then apply them to different" scenarios, the source says.

For example, in the 1994 cancer PCBs assessment, the high risk and persistence tier, with a slope factor of 1-2 milligrams per kilogram body weight per day (mg/kd-day) is to be used in cases where there were instances of: "[f]ood chain exposure"; "[s]ediment or soil ingestion"; "[d]ust or aerosol inhalation"; "[d]ermal exposure, if an absorption factor has been applied"; "[p]resence of dioxin-like, tumor-promoting, or persistent congeners" and/or "[e]arly-life exposure (all pathways and mixtures)."

The assessment provides a range of slope factor for the low risk tier of 0.3-0.4 milligrams per kilograms of body weight per day (mg/kg-day) to be used with "[i]ngestion of water-soluble congeners"; "[i]nhalation of evaporated congeners" and/or "[d]ermal exposure, if no absorption factor has been applied." The lowest risk tier gives a slope factor range of 0.04-0.07 mg/kg-day with instructions to use this potency range if "[c]ongener or isomer analyses verify that congeners with more than 4 chlorines comprise less than 1/2% of total PCBs."
Agency sources indicate that since the last assessments were published, there are new animal and human data indicating that some PCBs pose non-cancer risks as well as cancer risks, and particularly, that inhalation can be a pathway of concern. It is the suggestion of these new risks that led to the decision to undertake a non-cancer assessment, the sources say.
Pat Casano, an attorney for General Electric Co., raised similar concerns as ACC's Beck, and urged the agency to limit the scope of its assessment to make it more feasible. "This will be an extremely difficult, if not impossible [assessment] because you're going to look at all 209 congeners," Casano said. Instead, she

suggested that perhaps EPA try to focus on the PCBs in caulk, and questioned the feasibility of risk management of other areas of concern, such as the presence of PCBs in human breast milk.

"Is there anything that can be done about breast milk?" she asked, citing declining levels of PCBs in the environment and the billions she said have been spent cleaning up waste sites, renovating buildings, and other cleanup projects targeting PCBs. "That would be information that would be helpful to understand to focus your work."

The June meeting is an early step in EPA's efforts to craft an IRIS assessment. IRIS staff presented a draft planning and scoping document for discussion. The document is intended to outline information IRIS staff have gleaned from a preliminary literature search and begin to form EPA's plans for the assessment by discussing which exposure routes -- ingestion, inhalation or dermal -- are of interest to agency decision makers.

In its planning and scoping document, EPA explains that it intends to "evaluate non-cancer human health hazards associated with PCB exposure through oral, inhalation and dermal routes, provided adequate data are available. Dose-response information for identified hazards will also be included when feasible because this information can be useful for both characterizing risks at varying exposure levels and analyzing benefits associated with reducing exposures. A dose-response assessment for the dermal route of exposure is not planned at this point because oral and inhalation exposure are generally considered the major exposure routes. However, toxicokinetic data relevant to dermal exposure will be included to support the evaluation of potential risks from dermal exposures."

In comments submitted to EPA's docket, the Department of Defense (DOD) questions EPA's decision not to calculate dermal risk estimates in the PCBs assessment, calling it inconsistent with EPA's decision regarding its IRIS assessment of benzo(a)pyrene (BaP). "Given that Lehmann et al., 2015 … state that the major source of ingestion and inhalation of PCBs is dust in the house and given that

EPA assumes that household dust is mainly due to outdoor soil, IRIS should use the same assumptions it is using for BaP and [polycyclic aromatic hydrocarbons (PAHs)] regarding dermal exposures to contaminated dust and soil as these chemicals have similar properties," according to DOD's June 3 comments. "Please also explain why dermal exposure to BaP and PAHs is considered important and the same exposure is not for PCBs." -- *Maria Hegstad*

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